



Lum. 4.1-88  
August 16, 2005

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Hashem Akhavan-Tafti, Renuka de Silva, Robert A. Eickholt, C. William Gundlach, Richard S. Handley, Kenneth S. Lauwers, Mark D. Sandison and Wenhua Xie

Serial No.: 10/715,284                      Group Art Unit: 1637

Filed: November 17, 2003

For: CLEAVABLE SOLID PHASES FOR ISOLATING NUCLEIC ACIDS

Examiner: TBA

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97(b)(3)  
and 1.98**

Sir:

The information statement is being submitted before the issuance of a first Office Action. Provided herewith are a listing of references in the attached form PTO-SB/08 and copies of 5 non-U.S. Patent references. Applicants submit the references in the present case pursuant to their obligation under 37 CFR §§ 1.56, 1.97(b)(3) and 1.98. A concise statement of their relevance is either described in the specification of the subject application or is as follows.

References A-EE and UU-YY are described in the specification.

Reference FF (U.S. Patent 4,935,342) describes a method of purifying cellular or viral nucleic acids from a biological sample

purifying cellular or viral nucleic acids from a biological sample by binding nucleic acids to an anion exchange column material at a lower salt molarity than the molarity at which the target nucleic acids elute therefrom, washing said column with an aqueous salt solution of a second chloride molarity, and eluting the bound nucleic acids with a salt solution having a higher chloride molarity.

Reference GG (U.S. Patent 4,997,932) also describes a method of purifying nucleic acids from a biological sample by binding nucleic acids to an anion exchange column material and eluting sequentially with a low salt molarity solution and then with an high salt molarity solution.

Reference HH (U.S. Patent 5,057,426) describes a method for separating long-chain nucleic acids from other substances by fixing long-chain nucleic acids onto a porous anion exchanger matrix having a particle size of from about 15 to about 250  $\mu\text{m}$  and a pore diameter of about 100 to 2500 nm, washing the porous matrix to separate the other substances from the long-chain nucleic acids, and removing the fixed long-chain nucleic acids from the porous matrix.

Reference II (U.S. Patent 5,075,430) describes a process for purifying DNA from a liquid mixture by combining the liquid mixture with a chaotropic agent and contacting the resulting combination mixture with silica in the form of diatomaceous earth to selectively adsorb DNA, washing the silica with a buffer

containing from about 20% to about 95% of a lower alkyl alcohol to remove non-adsorbed matter, and eluting said DNA from said silica with water or a low salt buffer.

Reference JJ (U.S. Patent 5,155,018) describes a process for isolating biologically active RNA from a biological source by contacting said the source with particulate siliceous material in the presence of an acidified, concentrated chaotropic salt solution, to bind RNA to said particles, removing said particle-bound RNA from said source, and separating said biologically active RNA from said particles.

Reference KK (U.S. Patent 5,234,809) describes a process for isolating nucleic acid from a starting material by mixing the starting material, a chaotropic substance and a nucleic acid binding solid phase, separating the solid phase with the nucleic acid bound thereto from the liquid, and washing the solid phase nucleic acid complexes.

Reference LL (U.S. Patent 5,599,667) describes a method for purifying a polynucleotide greater than 100 nucleotides in a sample from shorter oligonucleotides 10 to 100 nucleotides long by contacting the sample with a solid support comprising a plurality of cations selected from ammonium, immonium and guanidinium ions, to bind the polynucleotide but not the shorter oligonucleotides, wherein the polynucleotide is at least three times longer than the shorter oligonucleotides, and separating the oligonucleotides from the support-bound polynucleotide.

Reference MM (U.S. 5,665,582) claims a method for reversibly

anchoring a biological material to a solid support having a reversible polymer placed thereon, attaching a reversible linker to the polymer, linking the biological material to the linker with a binding composition, and then subsequently releasing the biological material. The binding composition is defined as a separate substance, i.e. a complementary nucleic acid, an antibody or a binding protein, which is dispersed in or coated on the reversible polymer.

Reference NN (U.S. Patent 5,948,624) describes a method for isolating targets, including nucleic acids, from a mixture by reacting targets with a conjugate having a detector portion linked by a photocleavable portion to a coupling portion. Targets are chemically coupled to the conjugate, separated, and then photochemically cleaved. The methods differ from the present invention in requiring covalent attachment of target nucleic acids to small molecule cleavable conjugates.

Reference OO (U.S. Patent 6,027,945) describes a method for isolating a biological target material from other material in a medium by combining silica magnetic particles and the medium, binding the target material to the particles, removing the complex from the medium with an external magnetic field, and separating the biological target material from the complex by eluting the biological target material.

Reference PP (U.S. Patent 6,060,246) discloses a method for isolating or detecting in a sample a polynucleotide analyte having a target base sequence by using a rapid pairing reagent comprising

a solid substrate linked to a capture component and a target-specific probe. The capture component non-selectively binds to polynucleotide molecules, while the target-specific probe selectively binds the target base sequence of the polynucleotide analyte. The rapid pairing reagent-polynucleotide analyte complex is exposed to conditions which release the polynucleotide molecules from the capture component without disrupting said substrate-probe-target complex. The capture component can be an amine having a pKa of about 4-8 which binds polynucleotides at a pH below its pKa and releases them at a pH substantially above its pKa. The capture component can be linked to the substrate via a cleavable linkage.

Reference QQ (U.S. Patent 6,270,970) describes a mixed-bed solid phase and uses for isolating a target nucleic acid from a mixture. The solid phase comprises a first ion-exchanger solid phase which can bind to the target nucleic acid at a first pH, and release target nucleic acid at a second pH differing by at least 0.5 pH units; and a second ion-exchanger solid phase which can bind to the target nucleic acid at the second pH and release at the first pH; and both the first and second ion-exchangers having a capacity to release the bound target nucleic acid in the presence of an elution buffer.

Reference RR (U.S. Patent 6,447,764) describes a method for isolating anionic organic substances such as nucleic acids from aqueous systems by reversibly binding the organic substances to non-crosslinked polymer nanoparticles in cationic, protonated

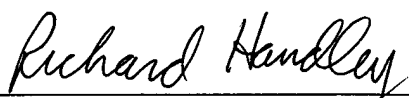
form, forming charged polymer nanoparticles, separating the charged polymer nanoparticles from the aqueous system, and releasing the organic substance from the nanoparticles by raising the pH to deprotonate the positively charged groups.

Reference SS (U.S. Patent 6,780,327) describes a positively charged porous membrane for separating negatively charged molecules from a solution. The positive charge can be supplied by a pendant quaternary ammonium group. No cleavable linkers are disclosed.

Reference TT (U.S. Patent 6,914,137) describes a solid phase for reversibly binding nucleic acids in a sample, the product comprising a plurality of immobilized positively ionizable groups which bind nucleic acid at a first pH at which the ionizable groups are positively charged and release the nucleic acid at a second, higher, pH at which the charge on the ionizable groups is negative, neutral or less positive.

Reference WW (Eur. Patent EP01036082) describes a method of extracting a nucleic acid from a sample using the materials as described in related U.S. Patent 6,914,137.

Respectfully submitted,

  
Richard S. Handley, Ph.D.  
Registration No. 38,484



PTO/SB/08A (07-05)

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/75,284
		Filing Date	November 17, 2003
		First Named Inventor	Hashem Akhavan-Tafti
		Art Unit	
Examiner Name		Attorney Docket Number	Lumigen 4.1-88
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U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	A	US- 4699717	10-13-1987	Riesner	
	B	US- 5057426	10-15-1991	Henco	
	C	US- 4395271	07-26-1983	Beall	
	D	US- 4233169	11-11-1980	Beall	
	E	US- 4297337	10-26-1981	Mansfield	
	F	US- 4554088	11-19-1985	Whitehead	
	G	US- 5356713	10-18-1994	Charmot	
	H	US- 5395688	03-07-1995	Wang	
	I	US- 4774265	09-27-1988	Ugelstad	
	J	US- 5091206	02-25-1992	Wang	
	K	US- 5866099	02-02-1999	Owen	
	L	US- 6291166	09-18-2001	Gerdes	
	M	US- 4628037	12-09-1986	Chagnon	
	N	US- 4627040	06-09-1987	Jospehson	
	O	US- 4695393	09-22-1987	Whitehead	
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	Q	US- 4654267	03-31-1987	Ugelstad	
	R	US- 5411730	05-02-1995	Kirpotin	
	S	US- 5707559	01-13-1987	Schaap	

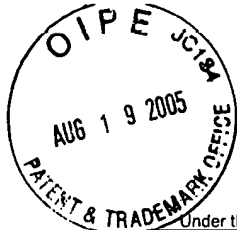
FOREIGN PATENT DOCUMENTS						
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	T	EP 0496822 B1	10-17-1990	Macherey		
	U	EP 1243649 A1	03-23-2001	Muller		
	V	EP 01036082	05-29-2002	Baker		
	W	03/053934 PCT Publication	07-03-2003	Akhavan-Tafti		

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 of 4

**Complete if Known**

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	X	US- 5707559	01-13-1998	Schaap	
	Y	US- 5578253	11-26-1996	Schaap	
	Z	US- 6063892	03-14-2000	Arghavani	
	AA	US- 6218135	04-17-2001	Matsumoto	
	BB	US- 6228653	05-08-2001	Matsumoto	
	CC	US- 5603868	02-18-1997	Wang	
	DD	US- 6107036	08-22-2000	Heindl	
	EE	US- 4952707	08-28-1990	Edwards	
	FF	US- 6140495	10-13-2000	Bronstein	
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	HH	US- 6461876	08-21-2000	Brij	
	II	US- 5770743	06-23-1998	Schaap	
	JJ	US- 4935342	06-19-1990	Seligson	
	KK	US- 4997932	03-05-1991	Reardon	
	LL	US- 5057426	10-15-1991	Henco	
	MM	US- 5057430	12-24-1991	Little	
	NN	US- 5155018	10-13-1992	Gillespie	
	OO	US- 5234809	08-10-1993	Boom	
	PP	US- 5599667	02-04-1997	Arnold	

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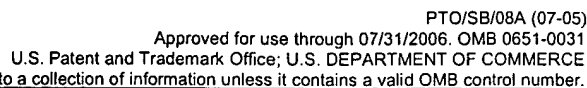
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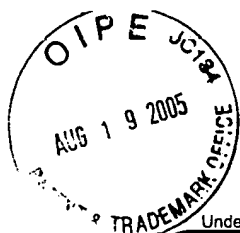
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	YY	Advanced Chem Tech 2003, catalog, pp. 105-150	

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